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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,581

02/05/2004

Richard S. Ginn

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

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06/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/773,581	Applicant(s) GINN, RICHARD S.	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/26/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 03/21/2007.

Allowable Subject Matter

2. The indicated allowability of claims 6 and 16-20 is withdrawn in view of the newly discovered reference(s) to Kaladelfos. Rejections based on the newly cited reference(s) follow.

Drawings

3. The drawings were received on 03/21/2007. These drawings are acceptable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701 A1) in view of Wedeen (U.S. Patent 4,606,335)

Regarding claim 1, Kuslich discloses a device comprising a band of biocompatible material having a first end and a length sufficient enough to wrap around the exterior of a spinal disc. Regarding claim 3, Kuslich discloses a device wherein the first end of the band element comprises an opening. Regarding claim 4, Kuslich discloses a device wherein the width is sufficient enough to cover a spinal disc and at least a partially cover at least one of the adjacent vertebrae. Regarding claims 5 and 6,

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Kuslich discloses a device that is capable of further comprising a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite on at least one side of the band. Regarding claims 7 and 8, Kuslich discloses a device that maybe comprised of nonporous or porous materials depending on the intended use of the device. Regarding claim 10, Kuslich discloses a device comprising a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Regarding claim 11, Kuslich discloses an embodiment of the device wherein the second end of the device is capable of being tied to another portion of the device and would require at least one thread extending from the second end of the device. Regarding claims 12 and 13, Kuslich discloses a device further capable of conducting electricity and having a power supply attached to the device to stimulate bone growth. Regarding claim 1, Kuslich fails to disclose a device further comprising an elongate member comprising a handle on the proximal end and a connector element on the distal end. Wedeen teaches a device that is an elongated member comprising a handle on the proximal end and a connector element on the distal end wherein the connector element is a hook (claim 2) in order to position a cerclage device around a bone (column 1 lines 5-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Kuslich with an elongated member comprising a handle on the proximal end and a connector element on the distal end in view of Wedeen in order to position a cerclage device around a bone.

6. Claims 1-8, 10-13, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Kaladelfos (U.S. Patent 6,494,887).

Regarding claim 1, Kuslich discloses a device comprising a band of biocompatible material having a first end and a length sufficient enough to wrap around the exterior of a spinal disc. Regarding claim 3, Kuslich discloses a device wherein the first end of the band element comprises an opening. Regarding claim 4, Kuslich discloses a device wherein the width is sufficient enough to cover a spinal disc and at least a partially cover at least one of the adjacent vertebrae. Regarding claims 5 and 6, Kuslich discloses a device that is capable of further comprising a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite on at least one side of the band. Regarding claims 7 and 8, Kuslich discloses a device that maybe comprised of nonporous or porous materials depending on the intended use of the device. Regarding claim 10, Kuslich discloses a device comprising a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Regarding claim 11, Kuslich discloses an embodiment of the device wherein the second end of the device is capable of being tied to another portion of the device and would require at least one thread extending from the second end of the device. Regarding claims 12 and 13, Kuslich discloses a device further capable of conducting electricity and having a power supply attached to the device to stimulate bone growth. Regarding claims 1 and 16, Kuslich fails to disclose the device further comprising an elongate member, wherein the elongated member includes a proximal

end including a handle and a curved distal end including a connector and a guide member, wherein the guide member includes a proximal end and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of an elongate element to pass. Kaladelfos teaches an instrument comprising an elongate member, wherein the elongated member includes a proximal end including a handle and a curved distal end including a connector and a guide member, wherein the guide member includes a proximal end and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of an elongate element to pass in order to insert an elongate element into a patient (column 1 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Kuslich further comprising an instrument comprising an elongate member, wherein the elongated member includes a proximal end including a handle and a curved distal end including a connector and a guide member, wherein the guide member includes a proximal end and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of an elongate element to pass in view of Kaladelfos in order to insert an elongate element into a patient.

Regarding claim 17, the combination of Kuslich and Kaladelfos disclose a device wherein the lumen comprising a slot wherein the height is greater than a width of the

elongate element. Regarding claim 18, the combination of Kuslich and Kaladelfos disclose a device wherein the proximal end of the guide member defines an axis, wherein the distal end of the guide member terminated in a distal tip extending transversely with respect to the axis. Regarding claim 19, the combination of Kuslich and Kaladelfos disclose a device wherein the height of the lumen extends substantially perpendicular to the radius of curvature of the distal end.

Regarding claim 20, the combination of Kuslich and Kaladelfos disclose the invention as claimed except for the device comprising a pair of guide handles. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Kuslich modified by Kaladelfos including a pair of guide member, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Allowable Subject Matter

7. Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 03/21/2007 have been fully considered but they are not persuasive. Regarding applicant's argument that the Kuslich reference and the Wedeen reference cannot be properly combined is not persuasive. Kuslich discloses a band capable of being used as a cerclage device on the spine as discussed above. Wedeen

discloses a device for inserting cerclage devices into the body. The examiner believes it is proper to combine a device capable of being used a cerclage device with an instrument for inserting a cerclage device into the body. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969. In this case, Kuslich discloses a device capable of being used as a cerclage device on the spine and Wedeen discloses a device for inserting cerclage devices into the body. Wedeen suggests to one having ordinary skill in the art to use a device to insert a

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cerclage device into the body. The examiner has withdrawn previously indicated allowability of claims 6 and 16-20 and presented new grounds of rejection for claims 6 and 16-20 as discussed above, since previously indicated allowability has been withdrawn and new grounds of rejection have been presented this office action is non-final.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER